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FEE TRANSMITTAL
For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 500.00

Complete if Known	
Application Number	10/027,134-Conf. #4419
Filing Date	December 20, 2001
First Named Inventor	Parris S. Wellman
Examiner Name	A. F. Roane
Art Unit	3739
Attorney Docket No.	102863-0017RCE

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- =	_____	x	_____	=	_____

Multiple Dependent Claims: Fee ($) _____ Fee Paid ($) _____

Indep. Claims		Extra Claims		Fee ($)		Fee Paid ($)
_____	- =	_____	x	_____	=	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	_____	/50	_____	(round up to a whole number) x	_____	=	_____

4. OTHER FEE(S) Fees Paid ($)

Non-English Specification, $130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1402 Filing a brief in support of an appeal 500.00

SUBMITTED BY					
Signature	Lisa Adams	Registration No. (Attorney/Agent)	44,238	Telephone	(617) 439-2000
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Fee Transmittal

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: December 23, 2005 Signature: Lisa Adams (Lisa Adams)

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PATENT

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the Application of	:	Parris S. Wellman et al.
Serial No.	:	10/027,134
Filed	:	December 20, 2001
Entitled	:	**BIPOLAR ABLATION ELECTRODES AND METHOD OF USE**
Docket No.	:	102863-17RCE

Group Art Unit: 3739

Examiner: Aaron F. Roane

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Mailing (37 C.F.R. 1.8(a))

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December 23, 2005
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By: Lisa Adams, Reg. No. 44,238

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc., a Johnson & Johnson company. Ethicon, Inc. of Somerville, New Jersey derives its rights in this application by virtue of an assignment of the application by the inventors to Ethicon, Inc. recorded at Reel 012412, Frame 149-151.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-4, 6-13, 15 and 16 are currently pending in the present application, Serial Number 10/027,134. According to the final Office Action mailed on July 25, 2005, claims 1-4, 7, 8, 10, 13, and 15 are finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,964,759 of Yamanashi et al. ("Yamanashi") in view of U.S. Patent No. 6,334,860 of Dorn ("Dorn"), and further in view of U.S. Patent No. 6,277,117 of Tetzlaff et al. ("Tetzlaff"). Dependent claims 6 and 16 are finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over Yamanashi in view of Dorn, and further in view of Tetzlaff as applied to claim 1, and further in view of U.S. Patent No. 6,514,252 of Nezhat et al. ("Nezhat"). Dependent claim 9 is finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over Yamanashi in view of Dorn, and further in view of Tetzlaff as applied to claim 1, and further in view of U.S. Patent No. 6,610,055 of Swanson et al. ("Swanson"). Dependent claim 12 is finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over Yamanashi in view of Dorn, and further in view of Tetzlaff as applied to claim 1, and further in view of U.S. Patent No. 6,102,909 of Chen et al. ("Chen").

Claims 1, 3, and 11, are also finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 2,888,927 of Fozard, in view of U.S. Patent No. 5,846,252 of Mehl, Sr. ("Mehl"), and further in view of U.S. Design Patent No. D452,936 of Grisoni.

Accordingly, claims 1-4, 6-13, 15 and 16 are subject to appeal.

IV. STATUS OF AMENDMENTS

Appellants filed an Amendment Pursuant to §41.33 on December 21, 2005, amending independent claims 1 and 13 to place the claims in better condition for appeal. The amendment to claim 13, however, contained typographical errors, and thus a Supplemental Amendment Pursuant to

§41.33 was filed on the same date to replace the previous amendment.

In the final Office Action dated July 25, 2005, the Examiner indicated that the language in claims 1 and 13 reciting "a substantially circular shape" is not sufficient to distinguish over U.S. Patent No. 6,277,117 of Tetzlaff et al., as it does not clarify that the cross-section is circular. The Examiner suggested that independent claims 1 and 13 be amended to clarify that the *cross-sectional* shape is circular. Accordingly, Appellants amended independent claims 1 and 13 to delete the phrase "with a substantially circular shape," and to recite that at least a portion of a cross-sectional shape of the tissue-contacting conductive element or surface is circular. Support for the amendment can be found throughout the specification and in the drawings, for example in paragraphs 0043 and 0044 of the published application. No new matter was added.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Cardiac arrhythmias, such as atrial fibrillation, are a commonly occurring disorder characterized by erratic beating of the heart. While medication can be an effective treatment for some cases, many patients are not responsive to medical therapies and require alternative treatment such as surgery. Known surgical techniques include the use of ablation devices to create tissue lesions in an affected portion of the heart in order to block electrical conduction. One common ablation technique employs the use of a catheter that is introduced into the heart (e.g. intravascularly) to direct radio-frequency (RF) energy at specific areas of heart tissue found to be the source of the irregular rhythms. The RF ablation techniques are typically successful in treating atrial fibrillation, however the lesions must be well defined within the heart to be effective. The lesions must have a sufficient length, continuity and/or depth to interrupt or block electrical conduction across the affected portion of the heart. This can be difficult to achieve without forming an incision in the atrium. In addition, if the energy is not uniformly transmitted to the target site, hot spots can form, possibly leading to severe tissue damage or blood coagulation (clots). Thus, the present invention provides ablation instruments for treating atrial fibrillation utilizing RF energy that produce uniform ablations with minimal risk of damage to the atria.

Independent claim 1 recites a surgical ablation instrument having first and second members pivotally coupled to one another and having tissue-contacting conductive elements extending along a length thereof and in communication with a source of ablative energy. At least a portion of a cross-sectional shape of each tissue-contacting conductive element is circular. Claim 1 also recites that the

second member includes a distal tissue-piercing tip adapted to be deployed into tissue to allow the first conductive element to be positioned on a first tissue surface and the second conductive element to be positioned on a second tissue surface opposed to the first tissue surface such that ablative energy can be transmitted between the first and second conductive elements.

Independent claim 13 recites an ablation instrument with first and second members that are opposed to and pivotally movable relative to one another. Each member includes a tissue-contacting conductive surface, and at least a portion of a cross-sectional shape of each tissue-contacting conductive surface is circular. Claim 13 further recites that the second member includes a distal tissue-piercing tip that is adapted to be selectively deployed into tissue to allow the tissue-contacting conductive surface of each of the members to be disposed on opposed sides of tissue. Claim 13 also recites first and second conductor elements mated to the first and second members. At least one of the conductor elements is effective to transmit ablative energy to the tissue-contacting conductive surface of at least one of the first and second members.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether the Examiner improperly rejects claims 1-4, 7, 8, 10, 13, and 15 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,964,759 of Yamanashi et al. in view of U.S. Patent No. 6,334,860 of Dorn, and further in view of U.S. Patent No. 6,277,117 of Tetzlaff et al.

B. Whether the Examiner improperly rejects claims 6 and 16 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,964,759 of Yamanashi et al. in view of U.S. Patent No. 6,334,860 of Dorn, and further in view of U.S. Patent No. 6,277,117 of Tetzlaff et al. as applied to claim 1, and further in view of U.S. Patent No. 6,514,252 of Nezhat et al.

C. Whether the Examiner improperly rejects claim 9 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,964,759 of Yamanashi et al. in view of U.S. Patent No. 6,334,860 of Dorn, and further in view of U.S. Patent No. 6,277,117 of Tetzlaff et al. as applied to claim 1, and further in view of U.S. Patent No. 6,610,055 of Swanson et al.

D. Whether the Examiner improperly rejects 1, 3, and 11 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 2,888,927 of Fozard, in view of U.S. Patent No. 5,846,252 of Mehl, Sr., and further in view of U.S. Design Patent No. D452,936 of Grisoni.

VII. ARGUMENT

A. Rejection of claims 1-4, 7, 8, 10, 13, and 15 pursuant to 35 U.S.C. §103(a) as being obvious over Yamanashi in view of Dorn, and further in view of Tetzlaff.

1. The Examiner's Rejection Over The Prior Art and the Scope and Content of the Prior Art

Independent claims 1-4, 7, 8, 10, 13, and 15 are finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,964,759 of Yamanashi et al. ("Yamanashi") in view of U.S. Patent No. 6,334,860 of Dorn ("Dorn"), and further in view of U.S. Patent No. 6,277,117 of Tetzlaff et al. ("Tetzlaff").

The Examiner argues that Yamanashi discloses the claimed invention, except for first and second members that are pivotally connected, and substantially circular conductive elements extending along the length of the first and second members. As shown in Figures 2, 3, and 4, Yamanashi discloses a surgical heating tool having two blades that are insulated along a length thereof, except along sharply pointed tip on each blade. One of the blades serves as an active blade, and the other blade is a passive blade that has no electrical connection. *See* Col. 3, lines 58-61. In use, radiofrequency energy is delivered to the active tip to cut and vaporize tissue in contact with the tip.

The Examiner admits that Yamanashi fails to disclose a pivot connection between the first and second blades, and first and second conductive elements connected to the first and second members, respectively. The Examiner argues, however, that

> [i]t is well known in the art to provide the first and second members disclosed by Yamanashi et al. with a pivotable connection in order to facilitate the opening and closing of the members with respect to each other and to place a first electrically conductive element on the first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping [sic] coagulating tissue grasping surfaces.

Office Action dated July 25, 2005, p. 3. As an illustrative example, the Examiner refers to Dorn, which discloses electrosurgical forceps having a pivot pin between first and second members to allow pivoting of the members, and first and second electrically conductive elements disposed on first and second members, respectively, to provide tissue grasping surfaces.

The Examiner admits that Yamanashi and Dorn both fail to teach first and second conductive

elements having a circular shape extending along a length thereof. The Examiner argues, however, that "it is well known in the art to provide forceps [sic] jaws with [a] substantially circular shape extending along the length of the jaws, or curved jaws in order to provide the necessary sealing along a particular desired path." *Id.* The Examiner thus relies on Tetzlaff to disclose an electrosurgical forceps device having curved jaws, arguing that "it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. . . . to provide curved forceps jaws in order to provide hemostatis along a desired non-linear path" as taught by Tetzlaff. *Id.* at p. 4.

The Examiner has failed to establish a prima facie case of obviousness for several reasons. At the outset, the combination of references does not teach the claimed invention. The Examiner has further failed to identify the motivation necessary to combine the references, and rather is improperly relying on hindsight to pick and choose among isolated features in the prior art to piece together the claimed invention. The Examiner has also overlooked that fact that the references represent non-analogous art that cannot be relied on to render the claimed invention obvious.

2. The Combination Of References Does Not Teach The Claimed Invention.

(a) Claims 1-4, 7, 8, and 10

As previously discussed, independent claim 1 requires a surgical ablation instrument having first and second members pivotally coupled to one another and having tissue-contacting conductive elements extending along a length thereof and in communication with a source of ablative energy. At least a portion of a cross-sectional shape of each tissue-contacting conductive element is circular.

The Examiner argues that Yamanashi teaches the claimed invention, except the Examiner admits that Yamanashi fails to teach a pivot connection between the first and second members, first and second conductive elements extending along a length of the first and second members, respectively, and that the conductive elements are substantially circular along the length of the first and second members as required by independent claim 1.

The Examiner has overlooked the fact that Yamanashi discloses a monopolar device, and thus fails to teach first and second tissue-contacting conductive elements in communication with a source of ablative energy, as required by independent claim 1. As explained at Col. 3, lines 58-61, "[o]ne of the blades serves as an active blade and is connected to the loading and tuning coil by means of a heavily insulated cable. The other blade of the surgical forceps is a passive blade and has

no electrical connection." Since only one of the blades has a wire that couples to an energy source, Yamanashi does not teach or even suggest first and second tissue-contacting conductive elements in communication with a source of ablative energy, as required by independent claim 1.

Yamanashi and Dorn also fail to teach or even suggest tissue-contacting conductive elements extending along the length thereof and having a cross-sectional shape with at least a portion that is circular, as further required by independent claim 1. Tetzlaff does not remedy the deficiencies of Yamanashi and Dorn. In an amendment filed on December 21, 2005, Appellants amended independent claim 1 to recite that at least a portion of a cross-sectional shape of the first and second tissue-contacting conductive elements is circular. Tetzlaff does not teach or even suggest first and second tissue-contacting conductive elements or surfaces having a cross-sectional shape with at least a portion that is circular. Rather, as shown best in FIG. 3, the jaws of Tetzlaff are substantially planar, and the conductive elements are in the form of electrodes (120, 121) that disposed on the distal-most tips thereof. The electrodes do not have a substantially circular cross-sectional, and they do not extend along the length of the jaws. Accordingly, Tetzlaff fails to remedy the deficiencies of Yamanashi and Dorn.

In sum, none of the cited references teaches or even suggests first and second tissue-contacting conductive elements in which at least a portion of a cross-sectional shape is circular. Claim 1 therefore distinguishes over Yamanashi, Dorn, and Tetzlaff, taken alone or combined. Claims 2-4, 7, 8, and 10 are allowable at least because they depend from allowable base claim 1.

(b) Claims 13 and 15

Independent claim 13 recites an ablation instrument with first and second members that are opposed to and pivotally movable relative to one another. Each member includes a tissue-contacting conductive surface, and at least a portion of a cross-sectional shape of each tissue-contacting conductive surface is circular. Claim 13 also recites first and second conductor elements mated to the first and second members.

The Examiner argues that Yamanashi teaches the claimed invention, except the Examiner admits that Yamanashi fails to teach a pivot connection between the first and second members, and substantially circular conductive surfaces extending along the length of the first and second members, as required by independent claim 13.

As previously discussed, the Examiner has overlooked the fact that Yamanashi discloses a monopolar device, and thus fails to teach first and second tissue-contacting conductive surfaces in communication with a source of ablative energy, as required by independent claim 13. As explained above, Yamanashi specifically states that only one of the blades is coupled to an energy source, and the other blade has no electrical connection. *See* Col. 3, lines 58-61. Since only one of the blades has a wire that couples to an energy source, Yamanashi does not teach or even suggest first and second conductor elements mated to the first and second members, as required by independent claim 13.

Yamanashi and Dorn also fail to teach or even suggest substantially tissue-contacting conductive surfaces extending along the length thereof and having a cross-sectional shape with at least a portion that is circular, as further required by independent claim 13. Tetzlaff does not remedy the deficiencies of Yamanashi and Dorn. In an amendment filed on December 21, 2005, Appellants amended independent claim 13 to recite that at least a portion of a cross-sectional shape of the first and second tissue-contacting conductive surfaces is circular. Tetzlaff does not teach or even suggest first and second tissue-contacting conductive elements or surfaces having a cross-sectional shape with at least a portion that is circular. Rather, as shown best in FIG. 3, the jaws of Tetzlaff are substantially planar, and the conductive elements are in the form of electrodes (120, 121) that disposed on the distal-most tips thereof. The electrodes do not have a substantially circular cross-sectional, and they do not extend along the length of the jaws. Accordingly, Tetzlaff fails to remedy the deficiencies of Yamanashi and Dorn.

In sum, none of the cited references teaches or even suggests first and second tissue-contacting conductive surfaces in which at least a portion of a cross-sectional shape is circular. Claim 13 therefore distinguishes over Yamanashi, Dorn, and Tetzlaff, taken alone or combined. Claim 15 is allowable at least because it depends from an allowable base claim.

3. The Examiner Has Further Failed To Identify The Motivation Necessary To Combine The References.

The Examiner has also failed to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine the references. In combining references to support an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The teaching or motivation must come from the references, and it cannot be derived from

Appellant's teachings.

The Examiner argues that a person having ordinary skill in the art would have been motivated to modify Yamanashi in view of Dorn to include first and second conductive elements (claim 1) or surfaces (claim 13) extending along a length of the first and second members "in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces." Office Action dated July 25, 2005, p. 3. The Examiner has overlooked the fact that Yamanashi is specifically directed to a monopolar device having one active blade and one passive blade. The addition of first and second conductive elements or surfaces extending along a length of each blade, as taught by Dorn, is specifically contrary to the purpose and teachings of Yamanashi. The Examiner has also overlooked the fact that Yamanashi is directed to a cutting and coagulating device that is already sufficient to grasp and cut tissue. A person having ordinary skill in the art would not be motivated to modify a device to perform a function which it is already effective to perform. Accordingly, there is no motivation to modify Yamanashi in view of Dorn.

The Examiner's obviousness rejection can only be the product of impermissible hindsight. An Examiner may only establish a prima facie case of obviousness when "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). In asserting that the prior art "suggested" the claimed subject matter, however, an Examiner must realize that "the mere fact that the prior art may be modified in the manner proposed by the Examiner neither makes the modification prima facie obvious nor obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). "[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Werner Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Moreover, the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *Id.* The Federal Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.*

Applicants were motivated by problems discovered, and which were not recognized by Yamanashi, Dorn, or Tetzlaff, to develop a unique configuration for an ablation instrument. The

Examiner's picking and choosing of features out of context from three different references in an attempt to construct a prima facie obviousness rejection boils down to an impermissible hindsight reconstruction of Applicant's invention. Applicant's claimed invention is patentable over the combination of Yamanashi, Dorn, or Tetzlaff.

4. The References Are Non-Analogous Art.

The cited references also represent non-analogous art that cannot be relied on to formulate an obviousness rejection over the pending claims. In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is "analogous" if (1) the reference is within the field of the inventor's endeavor, and if it is not then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved. Yamanashi, Dorn, and Tetzlaff are not within the field of the inventor's endeavor, and they are certainly not reasonably pertinent to the problem to be solved.

Yamanashi, Dorn, and Tetzlaff are directed to tools used to ***coagulate*** or ***cut*** tissue. The present invention, on the other hand, is directed to an ablation device for use in ***ablating*** tissue. The Examiner argues that "coagulation and ablation are interpreted as the same, generally, devices that can coagulate tissue and also ablate tissue." Office Action dated July 25, 2005, p. 14. Applicants disagree. The term "coagulate" is typically understood to mean to clot, or change from a liquid to a solid. The term "ablation," on the other hand, involves burning the tissue. These are very different procedures with different purposes. No person having ordinary skill in the art would combine various references directed to cutting or coagulating tools to arrive at an ablation tool. Accordingly, the cutting and coagulating tools disclosed by Yamanashi, Dorn, and Tetzlaff are not within the field of Appellant's endeavor, namely ablation.

Yamanashi, Dorn, and Tetzlaff are also not reasonably pertinent to the problem being solved by the applicants of the claimed invention. The present invention is directed toward an ablation instrument that can be used to form an ablative lesion uniformly through an entire thickness of tissue, e.g., the myocardial wall. The tissue-piercing tip of one of the members allows the members to grasp tissue therebetween the form a uniform lesion. Yamanashi, Dorn, and Tetzlaff, on the other hand, are specifically directed toward improved cutting and coagulating tools. In particular, Yamanashi is directed to a monopolar electroconvergent cautery system that does not require the use of a solenoid coil or a grounding component. Dorn is directed to a means for electrically insulating a miniaturized

configuration of the jaw parts of a bipolar medical instrument. Tetzlaff is directed to forceps having a removable and disposed electrode assembly that mates thereto. None of these references are pertinent to forming a uniform lesion through an entire thickness of tissue, and in fact none of the references even teach or suggest any type of device that is capable of forming an ablative lesion. Accordingly, Yamanashi, Dorn, and Tetzlaff are also not pertinent to the problem being solved by the present invention, and therefore represent non-analogous art that cannot be relied on to reject the claimed invention.

B. Rejection of claims 6 and 16 pursuant to 35 U.S.C. §103(a) as being obvious over Yamanashi in view of Dorn, and further in view of Tetzlaff as applied to claim 1, and further in view of Nezhat.

1. Claim 6

Claim 6 depends from claim 1 and recites that the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member.

The Examiner admits that Yamanashi, Dorn, and Tetzlaff fail to teach first and second electrodes extending along a first member, and a single electrode extending along the second member. Thus, the Examiner relies on Nezhat to teach such a configuration. The Examiner argues that it would have been obvious to modify Yamanashi to include a first and second electrodes extending along the first member, and a single electrode extending along the second member "to provide an alternate jaw surface configuration." Office Action dated July 25, 2005, p. 6. Appellants disagree.

As previously explained, Yamanashi is specifically directed to a monopolar device. Thus, it would not have been obvious to modify the device of Yamanashi to include electrodes on both jaws, much less two electrodes on one of the jaws and one electrode on the other jaw. Moreover, one of the jaws of Yamanashi is already conductive, and thus it essentially forms an electrode. The use of an additional electrode would not contribute anything to the device.

Accordingly, claim 6 further distinguishes over Yamanashi, Dorn, Tetzlaff, and Nezhat.

Claim 6 is also allowable at least because it depends from allowable claim 1.

2. Claim 16

Claim 16 depends from claim 13 and recites that the tissue-contacting conductive surface of the first member has a surface area greater than a surface area of the tissue-contacting conductive surface of the second member. The Examiner admits that Yamanashi, Dorn, and Tetzlaff fail to teach such a configuration, thus the Examiner relies on Nezhat to teach first and second conductive surfaces having different surface areas. The Examiner does not provide any motivation for modifying Yamanashi in view of Nezhat, but merely refers to Figure 9D of Nezhat.

As explained above, no person having ordinary skill in the art would rely on Nezhat to modify the device of Yamanashi. Yamanashi is specifically directed to a monopolar device, wherein Nezhat is directed to a bipolar device. The use of varying surface areas between the two blades would not contribute anything to the teachings of Yamanashi. The different surface areas allows one of the conductive surfaces to function as a return electrode. Yamanashi does not need to use a return electrode, as it is a monopolar device.

Accordingly, claim 16 further distinguishes over Yamanashi, Dorn, Tetzlaff, and Nezhat. Claim 6 is also allowable at least because it depends from allowable claim 1.

C. Rejection of claim 9 pursuant to 35 U.S.C. §103(a) as being obvious over Yamanashi in view of Dorn, and further in view of Tetzlaff as applied to claim 1, and further in view of U.S. Patent No. 6,610,055 of Swanson

Claim 9, which ultimately depends from claim 1, recites that at least one of the first and second members is malleable. The Examiner admits that Yamanashi, Dorn, and Tetzlaff fail to teach malleable members. Thus, the Examiner relies on Swanson to disclose first and second malleable members, arguing that "it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Swanson et al., to provide the first and second members in a malleable form in order to be re-shaped by the physician as needed for particular procedures and body structures." Office Action dated July 25, 2005, p. 7. Applicants disagree.

It would not have been obvious to one of ordinary skill in the art to modify Yamanashi in view of Swanson because Swanson is directed to an ablation instrument. As explained above, Yamanashi is directed to a tool that is used for an entirely different purpose – namely, to cut and

coagulate tissue. No person having ordinary skill in the art would rely on a reference directed toward an ablation instrument to modify a reference directed toward a cutting and coagulating tool.

Accordingly, claim 9 further distinguishes over Yamanashi, Dorn, Tetzlaff, and Swanson. Claim 9 is also allowable at least because it ultimately depends from allowable claim 1.

D. Rejection of claims 1, 3, and 11 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 2,888,927 of Fozard, in view of U.S. Patent No. 5,846,252 of Mehl, Sr., and further in view of U.S. Design Patent No. D452,936 of Grisoni..

1. The Examiner's Rejection Over The Prior Art and the Scope and Content of the Prior Art

Claims 1, 3, and 11 are also rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 2,888,927 of Fozard ("Fozard"), in view of U.S. Patent No. 5,846,252 of Mehl, Sr. ("Mehl"), and further in view of U.S. Design Patent No. D452,936 of Grisoni ("Grosini").

Fozard discloses a device for removing hair that includes a gripping member, in the form of tweezers, and a high frequency generator for delivering current to the tweezers to destroy the root of a hair grasped therebetween. The Examiner argues that Fozard teaches the claimed invention, except for a second electrically conductive element on the second member, and first and second tissue contacting conductive elements that are substantially circular in shape and extend along a length of the first and second members.

Mehl, like Fozard, discloses a hair removal device having two tweezer arms that are substantially planar. Each tweezer arms includes a metal electromagnetic energy conduction pad. As shown in FIG. 2, the pads (24, 26) are substantially planar. The Examiner argues that it would have been obvious to modify Fozard to include a second conductive element or surface, as taught by Mehl. The Examiner admits, however, that the Fozard/Mehl combination fails to teach curved jaws. Grisoni discloses a design for precision tweezers. The Examiner relies on Grisoni to disclose curved jaws, arguing that it would have been obvious to modify the Fozard/Mehl combination to include curved jaws as taught by Grisoni.

Again, the Examiner has failed to establish a prima facie case of obviousness. Namely, the combination of references does not teach the claimed invention. The references also represent non-analogous art that cannot be relied on to reject the claimed invention.

2. The Combination Of References Does Not Teach The Claimed Invention.

While Applicants do not agree that it would have been obvious to modify Fozard in view of Mehl and Grisoni, even if the references could be combined the combination does not teach the claimed invention. None of the references teach or even suggest first and second members having conductive elements extending along a length thereof and having a cross-sectional shape with at least a portion of the shape being circular, as required by independent claim 1. Fozard and Mehl each disclose precision tweezers for removing hair. Only a distal tip of each tweezer is conductive, and the conductive member does not have a cross-sectional shape with at least a portion of the shape being circular. The conductive surface on each of the Fozard and Mehl tweezers is planar. Grisoni does not remedy the deficiencies of Fozard and Mehl, as Grisoni is merely directed to the ornamental design for a pair of tweezers having a curved configuration. The tweezers do not include any type of conductive element, much less one that extends along a length of first and second members and that has a cross-sectional shape with at least a portion of the shape being circular.

Accordingly, independent claim 1 distinguishes over Fozard, Mehl, and Grisoni, taken alone or combined. The Examiner rejects dependent claims 3 and 11 as being obvious over Fozard, Mehl, and Grisoni, however these claims are also allowable at least because they depend from an allowable base claim.

3. The References Are Non-Analogous Art.

Fozard, Mehl, and Grisoni are also non-analogous art that cannot be combined to arrive at the claimed invention. Fozard, Mehl, and Grisoni are not within the field of the inventor's endeavor, and they are not reasonably pertinent to the particular problem with which the inventor was involved. Fozard, Mehl, and Grisoni are directed to precision tweezers used to ***grasp and remove hair***. The present invention, on the other hand, is directed to an ablation device for use in forming an ***ablative lesion***. Tweezers used to grasp hair are clearly not within the field of applicants endeavor, and no person having ordinary skill in the art would combine various references directed to tweezers to arrive at an ablation tool. The tweezers disclosed by Fozard, Mehl, and Grisoni are also clearly not reasonably pertinent to the problem being solved by the applicants of the claimed invention, as none of the references are directed toward solving the problem of forming an ablative lesion uniformly through an entire thickness of tissue. Accordingly, Fozard, Mehl, and Grisoni are non-analogous art that cannot be relied on to reject the claimed invention.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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APPENDIX A: CLAIMS ON APPEAL

1. (Previously Presented) A surgical ablation instrument, comprising:

a first member having a first tissue-contacting conductive element extending along a length thereof, at least a portion of a cross-sectional shape of the first tissue-contacting conductive element being circular, the first tissue-contacting conductive element being in communication with a source of ablative energy; and

a second member having a second tissue-contacting conductive element extending along a length thereof, at least a portion of a cross-sectional shape of the second tissue-contacting conductive element being circular, the second tissue-contacting conductive element being in communication with a source of ablative energy, and the second member being pivotally coupled to the first member and including a distal, tissue-piercing tip adapted to be deployed into tissue to allow the first conductive element to be positioned on a first tissue surface and the second conductive element to be positioned on a second tissue surface opposed to the first tissue surface such that ablative energy can be transmitted between the first and second conductive elements.

2. (Original) The ablation instrument of claim 1, wherein the first and second members are movable between a first, open position and a second, closed position in which the first member is adjacent to the second member.

3. (Original) The ablation instrument of claim 2, further comprising an actuating member mated to the first and second members and effective to selectively move the members between the open and closed positions.

4. (Original) The ablation instrument of claim 3, wherein the first and second members are elongate and each member includes a proximal end mated to the actuating member, and a distal portion having the conductive element disposed thereon.

5. (Cancelled).

6. (Original) The ablation instrument of claim 4, wherein the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element

comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member.

7. (Original) The ablation instrument of claim 2, further comprising:

a first conductor element extending from the first conductive element and adapted to communicate with the source of ablative energy; and

a second conductor element extending from the second conductive element and adapted to communicate with the source of ablative energy.

8. (Original) The ablation instrument of claim 2, wherein one of the first and second conductive elements is an active energy transmitting electrode, and the other one of the first and second conductive elements is a return electrode.

9. (Original) The ablation instrument of claim 2, wherein at least one of the first and second members is malleable.

10. (Original) The ablation instrument of claim 2, further comprising an insulative coating disposed around a portion of at least one of the first and second members.

11. (Original) The ablation instrument of claim 3, wherein the actuating member comprises opposed first and second handles, wherein a force applied to bring the first and second handles in contact with each other causes opening of the first and second members.

12. (Original) The ablation instrument of claim 3, wherein the first and second members are biased to the closed position.

13. (Currently Amended) An ablation instrument, comprising:

first and second members opposed to and pivotally movable relative to each other, each member having a tissue-contacting conductive surface extending therealong, at least a portion of a cross-sectional shape of each tissue-contacting conductive surface being circular, and the second member including a distal tissue piercing tip that is adapted to be selectively deployed into tissue to allow the tissue-contacting conductive surface of each of the first and second members to be disposed

on opposed sides of tissue; and

first and second conductor elements mated to the first and second members, at least one of the first and second conductor elements being effective to transmit ablative energy to the tissue-contacting conductive surface of at least one of the first and second members.

14. (Cancelled)

15. (Previously Presented) The ablation instrument of claim 13, wherein the instrument further includes an actuating member mated to the first and second members that is effective to move the members between an open position and a closed position.

16. (Previously Presented) The ablation instrument of claim 13, wherein the tissue-contacting conductive surface of the first member has a surface area greater than a surface area of the tissue-contacting conductive surface of the second member.

17-19. (Cancelled).